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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,002	02/17/2004	Daniel F. Klessig	3670-P02652US01	9555

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,002	KLESSIG ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *10-23 and 33-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,4-9,24,25,27-30 and 32* is/are rejected.

7)☒ Claim(s) *2,3,26 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/17/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-9 and 24-32, in the reply filed on 09/06/05 is acknowledged. The traversal is on the ground(s) that the restriction requirement between inventions I and IV is not in accordance to the MPEP section 803.01 which requires that the inventions must be independent and distinct as claimed and must bear a serious search burden. This is not found persuasive because inventions I and IV are unrelated, and the coexamination of Group I and II will present a serious search burden upon the examiner, for the reasons as set forth in the last Office action. The invention of Group IV requires the use of products other than the nucleic acid of Group I, and the steps of identifying agents, treating host cells with said agents and assays using said agents are not required in the plant transformation method of Group I. Therefore, the search of Group I will not reveal all arts relevant to the patentability of the invention of Group IV. Therefore, if the product claims of Group I are found allowable, the method claims of group IV would not be rejoined. Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 10-23 and 33-43 are withdrawn from consideration as being directed to the non-elected invention.

Claims 1-9 and 24-32 are examined.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

At claim 3, "a sequence" should be changed to ---the sequence--- because it refers to specific sequence.

At claim 7, "An" should be changed to ---The--- because it refers to a previous claim.

At claim 8, "an" should be changed to ---the--- because it refers to a previous claim.

Claim 26 improperly depends from claim 24 because claims 24 and claim 1 do not recite SEQ ID NO: 36.

At claim 32, "further" should be inserted before "comprises", for clarification

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite for lacking proper method steps. Also, the claim lacks correlation between the preamble and the body of the claim. The preamble recites enhancing resistance of a plant, and the body of the claim recites overexpressing an SABP2 nucleic acid molecule in a plant cell. Dependent claims 25-27 do not obviate the rejection, therefore are included in the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-9 and 24, 26-30 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated nucleic acid of SEQ ID NO: 1, an expression vector, a host cell and transgenic plant and plant cell comprising it, and a method of transforming a plant with said nucleic acid for enhanced disease resistance, does not reasonably provide enablement for an isolated nucleic acid molecule comprising a sequence encoding a polypeptide of SEQ ID NO: 2, a complement of SEQ ID NO: 1, and a homolog thereof, a host cell and transgenic plant comprising it, and a method of inducing resistance against plant pathogens with said nucleic acid molecule . The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated nucleic acid molecule comprising a sequence encoding a polypeptide of SEQ ID NO: 2, a complement of SEQ ID NO: 1, and a homolog thereof, a host cell and transgenic plant comprising it, and a method of inducing resistance against plant pathogens with said nucleic acid molecule. The scope of the claims encompass a sequence of any size and length encoding a polypeptide sequence of any size and length of SEQ ID NO: 2, and a complement of any size and any length of SEQ ID NO: 1, from any source. In contrast, the specification teaches the isolated nucleic acid molecule of SEQ ID NO: 1, host cells and plants transformed with an expression vector comprising said nucleic acid molecule and transformation of plants with said nucleic acid molecule to enhance disease resistance.

Applicant has not taught the obtention and use of nucleic acid molecules as broadly claimed. Applicant has not provided guidance which "a sequence or region" in the full length sequence of SEQ ID NO: 1 is essential to encode "a polypeptide" having the activity of SEQ ID NO: 2. Applicant does not teach transgenic plant/cells having resistance against exemplified or non-exemplified pathogens as a result of expressing said "a sequence" encoding "a polypeptide and homologs of SEQ ID NO: 2. Also, the specification is not enabling transformation of mammalian cells with said nucleic acids from tobacco. While the specification discloses sequences from Arabidopsis designated as homologs of the tobacco SABP2, none has been expressing in a transgenic plant to show SA-binding or disease resistance activity. Therefore, one skilled in the art who is

willing to practice the claimed invention would have to proceed trial and error experimentation to identify which sequence size within the 1000 bp sequence of SEQ ID NO: 1 would encode a functional SABP2 when expressed in transgenic plants.

The state of the art for isolating nucleic acid molecules with specified function is highly unpredictable. Substantial guidance is required with respect to hybridization/wash conditions that would allow the specific isolation of the target nucleic acid molecules. In the absence of such guidance, one skilled in the art has to proceed with trial and error experimentation to screen through the vast number of cDNA and genomic clones from all natural sources to identify nucleic acids homologs of SABP2 having the desired functional activity, and to evaluate the ability of said nucleic acids to enhance resistance in a transgenic against various bacteria, fungi, nematodes, and virus pathogens.

The working example disclosed in the specification is limited to the isolated nucleic acid molecule of SEQ ID NO: 1, the ability of said nucleic acid molecule to enhance resistance against specific pathogens cannot be extrapolated to "a" sequence thereof encoding "a" polypeptide retaining the function of SEQ ID NO: 2 or a homolog thereof, absent specific guidance.

When *In re Wands* factors (858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir, 1988).) are considered, the claimed invention is not enabled throughout the broad scope.

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991), where it is taught that the disclosure of a single gene sequence did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1, 4-9 and 24, 26-30 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to an isolated nucleic acid molecule comprising a sequence encoding a polypeptide of SEQ ID NO: 2, a complement of SEQ ID NO: 1, and a homolog thereof, a host cell and transgenic plant comprising it, and a method of inducing resistance against plant pathogens with said nucleic acid molecule. The scope of the claims encompass a sequence of any size and length encoding a polypeptide sequence of any size and length of SEQ ID NO: 2, and a complement of any size and any length of SEQ ID NO: 1, from any source. In contrast, the specification describes the isolated nucleic acid molecule of SEQ ID NO: 1, host cells and plants transformed with an expression vector comprising said nucleic acid molecule and transformation of plants with said nucleic acid molecule to enhance disease resistance.

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that held that human insulin-encoding cDNA is not described by

prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity...Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes...does not necessarily describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA....Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus...a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA...A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition and structure of all homologs of the disclosed sequences encoding polypeptides having the functional activity of SEQ ID

NO: 2. While the specification discloses 18 other sequences identified as SABP homologs, all 18 sequences are from a single plant species, namely, Arabidopsis, and none have been expressed in a transgenic plant for SA binding activity. Applicant has not described structural elements common to all SABP genes, and a review of the literature does not indicate that such structural elements are well known to a skilled artisan. Consequently, the claimed methods that uses said nucleic acid homologs and, vectors, expression vectors and transformed plants/cells comprising said nucleic acids are not described.

The *University of Rochester v. G.D. Searle* & Co., Inc. (, U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L,) decided 05 March 2003, at page 8, bottom paragraph, that method claims are properly subjected to a written description requirement if the starting material which requires that method is itself inadequately described. The court specifically stated, "(T)he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment. It means little to "invent" a method if one does not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real;..... and there is no meaningful possession of the method."

Therefore, the claimed invention does not meet the current written description requirements. See, also, the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-9 and 24, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Klessig et al (US 5,977,442).

The claims are broadly drawn to an isolated nucleic acid molecule comprising "a" sequence encoding "a" polypeptide of SEQ ID NO: 2, a complement of SEQ ID NO: 1, and a homolog thereof, a host cell and transgenic plant comprising it, and a method of inducing resistance against plant pathogens with said nucleic acid molecule. The scope of the claims encompass a sequence of any size and length encoding a polypeptide sequence of any size and length of SEQ ID NO: 2, and a complement of any size and any length of SEQ ID NO: 1 or a homolog of said sequences in an expression vector, a host cell and plant and plant cell transformed with said sequence, and a method of transforming a plant with said nucleic acid molecule to enhance resistance against pathogen.

Klessig et al teach an isolated nucleic acid from tobacco encoding designated SIP having a role in signal transduction for the activation of plant defenses against pathogens a is induced by the salicylic acid agent. Klessig et al also teach a plasmid vector comprising said nucleic acid expression vector method of transforming a plant with said nucleic acid to enhance disease resistance, and transformed plant and plant

cells expressing said nucleic acid (column 5; Figs 3 and 5; column 9, last full paragraph; column 10; paragraph bridging pages 12-13; columns 18-20; and claims 1-10). The transgenic plant expressing said SIP polypeptide would inherently be fertile, absent evidence to the contrary. Therefore, Klessig et al teach all claim limitations, given that the nucleic acid sequence of the prior art is also from tobacco and is involved in the signal transduction for the activation of disease resistance, and is also SA inducible.

Remarks

Claims 2-3, 25-26, and 31-32 are free of the prior art because the prior art does not teach or reasonably suggest SEQ ID NO: 1, 2, or 36.

Claims 2-3 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/16/05

Mai

MEDINA A. IBRAHIM
PATENT EXAMINER